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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/726,024

12/02/2003

Manesh Dixit

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EXAMINER

CLAYTOR, DEIRDRE RENEE

ART UNIT

PAPER NUMBER

1617

MAIL DATE

DELIVERY MODE

12/17/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/726,024	DIXIT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 30-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's arguments filed on 8/18/2008 have been fully considered. Applicant's argue over the 35 USC 103 rejection and assert that the cited references fail to disclose or suggest the use of a hydrogel polymer in the core of a controlled release tablet. Applicants specifically point to the Mehta reference and claim that the teaching in Example 1 of HPMC E-6 as a hydrogel is incorrect and provide an article that indicates that HPMC E-6 has a viscosity range of 5-7 mPa's which is in contrast to the hydrogel polymer taught in the specification which has a viscosity range of 80,000 to 120,000 mPa's. Applicants assert that a high viscosity is required for a polymer to be considered a hydrogel polymer.

The Examiner has taken this argument into consideration and the arguments are not found persuasive. It is noted that the claims are drawn to a hydrogel polymer in claim 30 and claim 35 further limits the hydrogel polymer to particular polymers. Among those listed is hydroxypropyl methylcellulose in general. According to the teaching of the Rowe article supplied by the applicant, there are forms of hydroxypropyl methylcellulose that have higher viscosities and it is well within the skill of the art to choose a particular HPMC that has the appropriate viscosity for the composition to be formulated. Further, Mehta teaches the use of HPMC in general and specifies a particular species of that (HPMC E-6). However, as stated before, the claims list HPMC in general and the teachings of Mehta meet the claim limitation.

Applicants further argue that the Mulye reference would lead an individual of ordinary skill away from the presently claimed invention because Mulye discloses

Art Unit: 1617

multiparticulate dosage forms. Applicants also argue that Beiman teaches multiparticulate dosage forms but fails to mention methylphenidate.

It is noted that Mulye teaches a pharmaceutical composition that comprises a core element comprising a medicament and a coating comprised of an enteric polymer and a water insoluble polymer. Therefore Mulye was used for the teaching of a controlled release pharmaceutical compositions that comprise an enteric polymer. It is also noted that Beiman teaches enteric polymers contain processing aids to aid in delayed release of the drug and was used for this purpose and was not relied on for the teaching of methylphenidate.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicants also argue that the statement that the term "consisting essentially of" is not comprising language. Please refer to the MPEP 2111.03 and see the discussion referring to transitional phrases. It is noted that the transitional phrase "consisting essentially of" limits the scope of the claim to materials that do not materially affect the basic and novel characteristics of the claimed invention. It is further discussed that for

Art Unit: 1617

the purposes of searching and applying prior art, "consisting essentially of" will be construed as equivalent to "comprising".

The following rejections are given below for Applicant's convenience.

Absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" language of the instant claims will be construed as equivalent to "comprising". See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355.

### ***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al. (U.S. Patent 5,837,284) in view of Mulye (U.S. Patent 6,475,493) and Beiman et al. (U.S. Patent 6,312,728).

Mehta et al. teach an improved dosing of methylphenidate hydrochloride whereby two time-separated doses are provided via a single dosage unit, in which a first group of particles provides an immediate dose of methylphenidate in an amount from

Art Unit: 1617

about 2% to about 99% by weight and a second group of particles provides a second dose of methylphenidate in an amount from about 2% to about 75% with a binder (Col. 1, lines 13-17, Col. 3, lines 41-43, Col. 4, lines 12-14). Mehta et al. further teach a coating that delays the release of the methylphenidate (Col. 4, lines 32-36). The dosage unit is comprised of hydroxypropyl methylcellulose in an amount of 10 percent (Col. 10, lines 42-50). Mehta et al. further teach that the maximum concentration of the first dose occurs from about 1 hour to about 3 hours after ingestion, which is followed by a period when no drug is released which lasts approximately 2-6 hours, and the second dose is released about 6 hours following administration (Col. 5, lines 37-51 and Fig. 2).

Mehta et al. does not teach a diluent in the core, processing aids, that the coating is specifically made up of enteric coating polymers, a maximum plasma concentration and AUC<sub>0-24</sub>.

Mulye teaches a coating composition in a controlled release pharmaceutical composition which comprises an enteric polymer (Col. 4, lines 59-62). Active medications that can be used in the composition include methylphenidate (Col. 9, line 42). The compositions contain lactose in an amount of 2 to 70% (Col. 11, line 41) as well as colloidal silicon dioxide and magnesium stearate (Col.8, lines 4-5). Enteric polymers are present, including methacrylic acid copolymer (Col. 6, lines 28-29) and zein (Col. 12, line 22).

Similar to the teachings of Mehta et al. and Mulye, Beimen et al. teach oral dosage delivery systems comprised of a core comprising a therapeutic agent, an enteric polymer coating over said core, a coating of said therapeutic agent over enteric polymer

Art Unit: 1617

coat and a protective coating (Col. 7, lines 5-19). Beimen et al. teach that the enteric polymer coating may also contain processing aids (Col. 8, lines 8-10). The most preferred enteric coating is Eudragit L30D-55, which is a methacrylic acid copolymer, and is applied as a 45-55 % weight aqueous solution (Col. 9, lines 11-18).

Furthermore, it is obvious to vary and/or optimize the weight of each ingredient in the controlled release formulation according to the guidance provided by Mehta et al. and Mulye, to ensure that the proper amount of drug is released at the designated time interval. It is noted that “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

The dissolution profile, maximum plasma concentration and AUC of the controlled release methylphenidate tablet as claimed in claims 30-32, 43-47 and 49-54 is considered a property of the controlled release tablet of the invention. If the prior art has the same components, then the properties of the composition will necessarily follow. Because the combination of the prior art renders the claimed controlled release formulation obvious, the dissolution profile would be a property of the formulation. A compound and its properties are inseparable. In re Papesch, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the teachings of Mehta et al, which teach a composition for the improved dosing of methylphenidate, with Mulye and Beiman et al., which teach a controlled release pharmaceutical composition that comprises an enteric

Art Unit: 1617

polymer that aids in delayed release of the drug. One having ordinary skill in the art would have been motivated to combine the teachings of Mehta et al. with Mulye and Beiman et al. to formulate a controlled release composition of methylphenidate to reduce abuse potential and for better patient compliance to treat nervous system disorders (as taught by Mehta et al.; Col. 1, lines 26-32).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.



Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1617